

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARTHREX, INC.,
Petitioner,

v.

P TECH, LLC,
Patent Owner.

IPR2022-00787
Patent 9,999,449 B2

Before SHERIDAN K. SNEDDEN, MICHELLE N. WORMMEESTER,
and CYNTHIA M. HARDMAN, *Administrative Patent Judges*.

WORMMEESTER, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

Arthrex, Inc. (“Petitioner”) filed a Petition (Paper 2, “Pet.”) requesting *inter partes* review of claims 1–11 of U.S. Patent No. 9,999,449 B2 (Ex. 1001, “the ’449 patent”). P Tech, LLC (“Patent Owner”) did not file a preliminary response. Pursuant to 35 U.S.C. § 314, we instituted an *inter partes* review of all the challenged claims based on all the grounds presented in the Petition. Paper 6 (“Inst. Dec.”).

After institution, Patent Owner filed a Response (Paper 11, “PO Resp.”) to the Petition, Petitioner filed a Reply (Paper 15, “Pet. Reply”), and Patent Owner filed a Sur-reply (Paper 19, “PO Sur-reply”).

On July 20, 2023, we conducted an oral hearing. A copy of the transcript (Paper 24, “Tr.”) is in the record.

We have jurisdiction under 35 U.S.C. § 6(b). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a). For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–11 of the ’449 patent are unpatentable.

II. BACKGROUND

A. *Related Proceedings*

The parties identify one related federal district court case involving the ’449 patent, *P Tech, LLC v. Arthrex, Inc.*, Case No. 1-21-cv-00968 (D. Del.). Pet. viii; Paper 4, 2 (Mandatory Notices of the Patent Owner). The parties also identify two *inter partes* review proceedings involving other patents asserted in the district court case, namely, IPR2022-00717 and IPR2022-00786. Pet. viii; Paper 4, 2.

B. The '449 Patent

The '449 patent describes augmenting joints of the body, such as the knee. Ex. 1001, 1:15–21. For example, the '449 patent describes ligament augmentation. *See id.* at 24:28–26:35. Ligaments are soft tissue in or around a joint that hold the joint together while also controlling movements of the joint. *Id.* at 21:52–55. Ligament augmentation reinforces or supplements natural ligaments, including those that have been repaired or reconstructed. *Id.* at 24:30–49.

To illustrate, Figure 11A of the '449 patent is reproduced below.

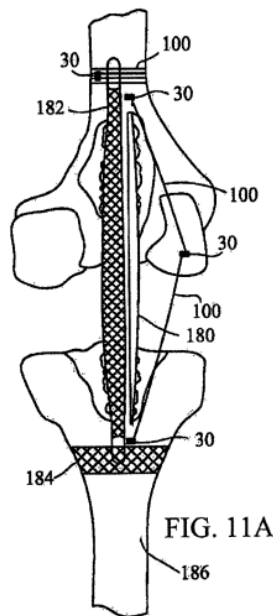


Figure 11A shows the augmentation of ligament 180. Ex. 1001, 8:34–35. A fastener 30 is placed near one end of ligament 180, while another fastener 30 is placed near the opposite end of ligament 180. *Id.* at 24:60–64. Two sutures 100, each of which is placed at an angle to ligament 180, are secured at their ends to fasteners 30 and tensioned between the fasteners. *See id.* at 24:64–25:4, Fig. 11A. This allows for “multiple-direction augmentation.” *Id.* at 25:5–7.

Tissue graft 182, which extends in a direction parallel to ligament 180, also is used to augment ligament 180. *Id.* at 25:8–13. The ends of graft 182 may be anchored to bone, ligament, or other tissue. *Id.* at 25:13–16. For example, as shown toward the top of Figure 11A, a fastener 30 is placed against tissue that is adjacent to graft 182, and a suture 100 is wrapped around graft 182 and the tissue multiple times to form a band. *Id.* at 25:20–24. As shown toward the bottom of Figure 11A, graft 182 also is secured to tissue (bone 186) using band 184, which is wrapped around graft 182 and bone 186. *Id.* at 25:29–33. Alternatively, one fastener may be placed in or against the graft, while another fastener may be placed in or against adjacent tissue, and the ends of a suture are secured to the fasteners and tensioned between them. *Id.* at 25:16–20.

C. Illustrative Claim

Petitioner challenges claims 1–11 of the '449 patent, where claim 1 is independent. Claim 1, reproduced below, is illustrative of the claims under challenge.

1. A surgical method for ligament augmentation comprising:
securing a first fastener at least partially within a first bone of a joint adjacent a first end of a ligament of the joint, wherein the first end of the ligament is attached to the first bone of the joint before securing the first fastener, and wherein a reinforcement component comprised of a multifilament structure fabricated from polyethylene and polyester is attached directly to the first fastener to anchor the reinforcement component to the first bone; and
securing a second fastener at least partially within a second bone of a joint adjacent a second end of the ligament of the joint opposite the first end of the ligament, wherein

the second end of the ligament is attached to the second bone of the joint before securing the second fastener, and wherein the reinforcement component is attached to the second fastener to anchor the reinforcement component to the second bone,

wherein the reinforcement component extends between the first and second ends of the ligament, and

wherein the reinforcement component is tensioned directly between the first and second fasteners.

D. Asserted Grounds of Unpatentability

Petitioner challenges claims 1–11 of the '449 patent on the following four grounds. Pet. 2, 20–66. We instituted *inter partes* review on all grounds. Inst. Dec. 30.

Claims Challenged	35 U.S.C. § ¹	References
1–4, 6	103	Van Kampen, ² Marshall ³
1–4, 6, 8	103	Van Kampen, Marshall, Lambrecht ⁴
5, 7–11	103	Van Kampen, Marshall, Boyce ⁵
5, 7, 9–11	103	Van Kampen, Marshall, Lambrecht, Boyce

¹ The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284 (2011), amended 35 U.S.C. § 103, effective March 16, 2013. Because the application from which the '449 patent issued claims the benefit of priority to an application that was filed before this date, the pre-AIA version of § 103 applies.

² Van Kampen, U.S. Patent No. 4,834,752, issued May 30, 1989 (Ex. 1005).

³ John L. Marshall et al., *The Anterior Cruciate Ligament: A Technique of Repair and Reconstruction*, in 143 CLINICAL ORTHOPAEDICS AND RELATED RESEARCH 97–106 (Marshall R. Urist, ed., 1979) (Ex. 1006).

⁴ Lambrecht, U.S. Patent No. 6,425,919 B1, issued July 30, 2002 (Ex. 1008).

⁵ Boyce et al., U.S. Publ’n No. 2004/0024457 A1, published Feb. 5, 2004 (Ex. 1007).

In support of the asserted grounds, Petitioner relies on a Declaration (Ex. 1002) as well as a Supplemental Declaration (Ex. 1016) of Dr. Steve E. Jordan, M.D. Transcripts of the depositions of Dr. Jordan are entered in the record as Exhibits 2002 and 2015.

Patent Owner relies on the Declaration of Dr. Robert A. Pedowitz, M.D., Ph.D. (Ex. 2001). Excerpts from the transcript of the deposition of Dr. Pedowitz are entered in the record as Exhibits 1017 and 1018.

III. DISCUSSION

A. Level of Ordinary Skill in the Art

In our Institution Decision, we determined that a person of ordinary skill in the art would have had a medical degree and at least two years of experience performing surgeries with implantable medical devices, such as suture anchors. Inst. Dec. 5–8. The parties do not dispute our determination. *See* PO Resp. 20 (“Patent Owner and Dr. Pedowitz, Patent Owner’s expert, agree with the Board’s analysis”); *see generally* Pet. Reply. Accordingly, we apply this level of ordinary skill in the art.

B. Claim Construction

In an *inter partes* review proceeding, we construe a claim of a patent “using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b).” *See* 37 C.F.R. § 42.100(b) (2019). That standard involves construing claims in accordance with the ordinary and customary meaning of such claims as would have been understood by one of ordinary skill in the art and the prosecution history

pertaining to the patent. *See id.*; *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–14 (Fed. Cir. 2005) (en banc).

Petitioner proposes a construction for the claim term “suture.” Pet. 17–18. Patent Owner responds that “this claim term does not need an express construction to resolve the issues presented in this Proceeding.” PO Resp. 21. Based on the complete record developed during trial, we conclude that no claim term requires express interpretation to resolve any controversy in this proceeding. *See Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

C. Obviousness over Van Kampen and Marshall

Petitioner asserts that claims 1–4 and 6 of the ’449 patent would have been obvious over Van Kampen and Marshall. Pet. 20–46. Patent Owner opposes. PO Resp. 21–47. For the reasons explained below, we determine that Petitioner has demonstrated by a preponderance of the evidence that claims 1–4 and 6 would have been obvious over Van Kampen and Marshall.

1. Overview Asserted Prior Art

We start with an overview of the asserted prior art, Van Kampen and Marshall.

a. Van Kampen

Van Kampen describes a tissue augmentation device for augmenting biological tissue used in ligament repair or reconstruction. Ex. 1005, 1:10–12, 2:23–32. To illustrate, Figure 1 of Van Kampen is reproduced below.

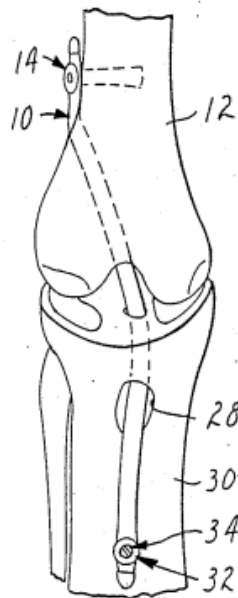


FIG. 1

Figure 1 shows a knee joint with augmentation device 10 in place. *Id.* at 3:1–2, 3:18–19. Device 10 has biological tissue sutured along its length. *Id.* at 3:19–20, 4:51–60. In ligament reconstruction, the tissue may be, for example, the patellar tendon or fascia lata. *Id.* at 4:66–5:4. In ligament repair, the tissue may be the damaged ligament itself. *Id.* at 5:4–8.

Device 10 is attached at one end to femur 12 by inserting legs of fastener 14 through braids at the end of device 10, a small hole created in the tissue, and a hole that has been drilled in femur 12. *Id.* at 3:20–22, 3:34–41. Device 10 extends from fastener 14 through tibial tunnel 28, and is attached at the other end to tibia 30 by inserting a cylindrical portion of bushing 32 through braids at the end of device 10, another small hole created in the tissue, and a hole in tibia 30. *Id.* at 3:47–52, 3:62–65. Screw 34 is inserted into bushing 32 and bored into tibia 30 to secure device 10 to tibia 30. *Id.* at 3:66–68.

Van Kampen explains that, in the early post-operative healing period, tissue loses strength because its normal blood supply is disrupted by the surgery. Ex. 1005, 1:25–30. The tissue eventually regains its strength, but, until then, the tissue must be protected from carrying normal loads. *Id.* at 1:30–34. Thus, device 10 is made from a material that has sufficient mechanical properties to support the working loads normally supported by the ligament. *Id.* at 2:23–37, 5:22–25, 5:43–49, 6:16–25. The material of device 10 is selected so that it will gradually lose some of its load-bearing capability after implantation, thereby gradually transferring increased loads to the tissue. *Id.* at 1:37–40, 6:16–25.

b. Marshall

Marshall is an article that discusses “the difficult technical aspects of both primary repairs and secondary reconstructions of ACL lesions alone,” where ACL refers to the anterior cruciate ligament. Ex. 1006, 97.

Regarding primary repairs in particular, Marshall describes passing a series of sutures in an anterior to posterior direction through the ligament, starting near the attached base and progressing toward the torn end. Ex. 1006, 98. For midportion tears, the sutures are placed in proximal and distal stumps. *Id.* The suture ends are divided into two groups, keeping the anteriorly and posteriorly exiting sutures separate. *Id.* The groups of sutures are brought out through separately drilled holes, and the suture ends are pulled tightly to eliminate slack. *Id.* The torn ends of the ligament are thus realigned. *Id.*

To illustrate, Figure 1 of Marshall is reproduced below.

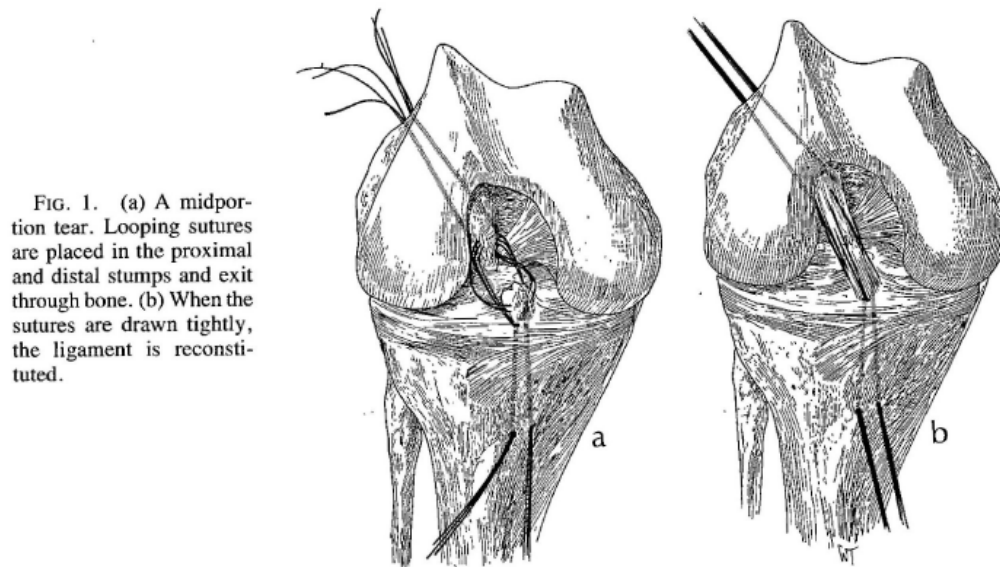


Figure 1 of Marshall shows a midportion tear in the ligament. Ex. 1006, 99. The left-hand view of Figure 1, designated by the letter “a,” shows looping sutures that are placed in proximal and distal stumps and exit through bone. *Id.* The right-hand view of Figure 1, designated by the letter “b,” shows that the ligament is reconstituted when the sutures are drawn tightly. *Id.*

2. Analysis of Claims 1–4 and 6

We now discuss claims 1–4 and 6 of the ’449 patent.

a. Independent Claim 1

Claim 1 is directed to “[a] surgical method for ligament augmentation” and recites various limitations, which Petitioner designates as limitations 1.1 through 1.8. We address the preamble and recited limitations, starting with Petitioner’s arguments, and then turning to the parties’ disputes.

i. Preamble

As noted above, the preamble of claim 1 recites “[a] surgical method for ligament augmentation.” Petitioner contends that, “[t]o the extent the preamble is deemed limiting, Van Kampen teaches a surgical method for ligament augmentation.” Pet. 23. As support, Petitioner directs us to where Van Kampen describes using its tissue augmentation device “in parallel with biological tissue in the repair or reconstruction of ligaments,” where “[t]he device is adapted for fixation at each end thereof to the anatomical structures connected by the ligament.” *Id.* at 22–23 (quoting Ex. 1005, code (57)).

Although we do not determine whether the preamble is limiting, we are persuaded by Petitioner’s argument and evidence that Van Kampen teaches the subject matter of the preamble. Patent Owner does not separately dispute Petitioner’s analysis for the preamble. *See generally* PO Resp.

ii. Limitation 1.1: “securing a first fastener”

Claim 1 recites “securing a first fastener at least partially within a first bone of a joint adjacent a first end of a ligament of the joint.” For this limitation, which Petitioner designates as limitation 1.1, Petitioner provides an annotated version of Figure 1 of Van Kampen, which is reproduced below. Pet. 24.

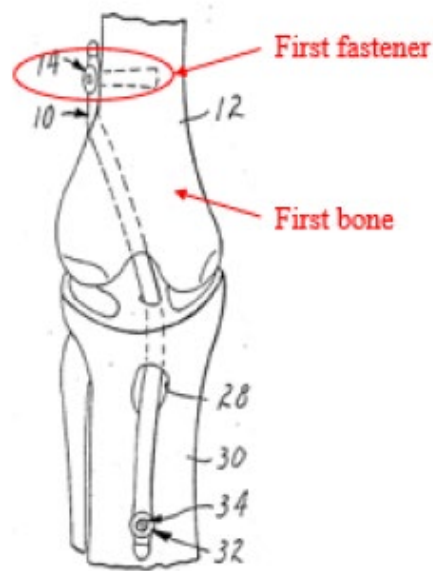


FIG. 1

Figure 1 of Van Kampen, as annotated by Petitioner, shows tissue augmentation device 10 implanted in a knee. *See* Ex. 1005, 3:17–19. Petitioner directs us to Van Kampen’s teaching that device 10 is “used in parallel with biological tissue for the repair or reconstruction of a ligament or tendon,” where “device [10] and the tissue are used adjacent to one another along their lengths,” and “device [10] is sutured or otherwise secured to the tissue along its length.” *Id.* at 4:51–60 (cited by Pet. 25). Petitioner also directs us to where Van Kampen teaches that, for ligament or tendon repair, “the biological tissue . . . is the damaged ligament or tendon itself which has been reapproximated by standard surgical techniques.” *Id.* at 5:4–8 (cited by Pet. 25).

Petitioner identifies Van Kampen’s fastener 14 as a “first fastener,” Van Kampen’s femur 12 as a “first bone,” and Van Kampen’s biological tissue, namely, the damaged ligament itself, as a “ligament.” *See* Pet. 24–25. As support, Petitioner further directs us to where Van Kampen teaches

that “[f]astener 14 is implanted by drilling a hole in the femur 12,” and that legs of fastener 14 “are inserted through the braids of one end of augmentation device 10 and a small hole created in the biological tissue,” and then “into the hole in the femur 12.” Pet. 24–25 (quoting Ex. 1005, 3:35–42). Petitioner additionally points to Van Kampen’s teaching that device 10 “augments the *entire length* of the tissue and . . . is affixed to bone at each end.” *Id.* at 25 (quoting Ex. 1005, 7:36–41 (emphasis added by Petitioner)). Petitioner contends that Van Kampen’s “fastener is placed near the end of the ligament (or replacement tissue), as Van Kampen teaches that the augmentation structure must extend ‘the entire length,’ i.e., between both ends of the ligament.” *Id.*

Patent Owner disputes Petitioner’s analysis for limitation 1.1. PO Resp. 24–29. We address the parties’ arguments below.

iii. Limitation 1.2: “first end of the ligament”

In connection with the step of “securing a first fastener,” claim 1 further limits the recited first end of the ligament. Specifically, claim 1 recites “wherein the first end of the ligament is attached to the first bone of the joint before securing the first fastener.” For this limitation, which Petitioner designates as limitation 1.2, Petitioner relies on Marshall. Pet. 27–29 (citing Ex. 1006, 98–100). As discussed above, “the damaged ligament . . . which has been reapproximated by standard surgical techniques” in Van Kampen corresponds to the recited ligament. According to Petitioner’s declarant Dr. Jordan, “a scenario wherein the native tissue is reapproximated is typically referred to as ligament ‘repair.’” Ex. 1002 ¶ 51 (cited by Pet. 11–12).

Petitioner points to Marshall as “disclos[ing] in more detail a method for repairing a ligament in which the first and second ends of a ligament are attached to first and second bones (the bones to which the damaged ligament was originally attached), or portions thereof are more securely attached if the original ligament is being used and intact.” Pet. 27 (citing Ex. 1006, 98–100). Petitioner asserts that Marshall describes “a technique to repair a torn ACL in which sutures are passed through the proximal and distal stumps (ends) of the torn ligament, the sutures are passed through holes drilled in the bone on either side of the ligament, and then the sutures are tied down.” *Id.* (citing Ex. 1006, 98). To illustrate, Figure 1 of Marshall is reproduced below.

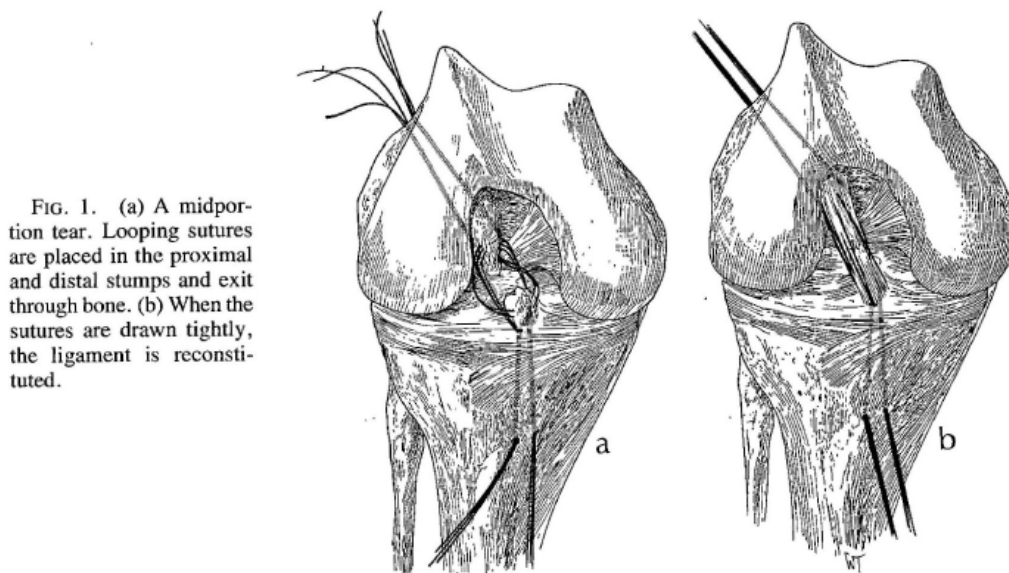


Figure 1 of Marshall shows a midportion tear in the ligament. Ex. 1006, 99. The left-hand view of Figure 1 shows looping sutures that are placed in proximal and distal stumps and exit through bone. *Id.* The right-hand view of Figure 1 shows that the ligament is reconstituted when the sutures are drawn tightly. *Id.*

Petitioner contends that, “[b]ecause the fastener in Van Kampen is being used to attach an augmentation device for a repaired or reconstructed ligament, a [person of ordinary skill in the art] would have appreciated that the fastener would have been secured in place after the ligament is repaired,” for example, “in a manner described in Marshall.” Pet. 28–29. In support of this contention, Petitioner reiterates that the damaged ligament in Van Kampen “has been reapproximated.” *Id.* at 29 (citing Ex. 1005, 5:4–8). Petitioner adds that “the tissue augmentation device in Van Kampen ‘is adapted for fixation at each end thereof to the anatomical structures connected by the ligament or tendon’ (Ex. 1005, 2:32–34), which confirms the ligament is attached to the first bone before the first fastener is inserted.” Pet. 29. Petitioner relies on the declaration testimony of Dr. Jordan. *Id.* (citing Ex. 1002 ¶ 79).

Based on Petitioner’s argument and evidence, we are persuaded that Petitioner’s proposed combination of Van Kampen and Marshall teaches limitation 1.2 of claim 1. Patent Owner does not separately dispute Petitioner’s showing in this regard. *See generally* PO Resp.

Patent Owner disputes, however, Petitioner’s proffered rationale for combining Van Kampen and Marshall. PO Resp. 29–46. We address the parties’ arguments below.

iv. Limitation 1.3: “reinforcement component”

Also in connection with the step of “securing a first fastener,” claim 1 further recites “wherein a reinforcement component comprised of a multifilament structure fabricated from polyethylene and polyester is attached directly to the first fastener to anchor the reinforcement component

to the first bone.” For this limitation, which Petitioner designates as limitation 1.3, Petitioner identifies Van Kampen’s tissue augmentation device 10 as a “reinforcement component.” Pet. 30.

Van Kampen’s device 10 has “a strap-like element which provides permanent augmentation of the tissue.” Ex. 1005, 5:22–25. Petitioner directs us to where Van Kampen teaches that “[m]aterials which are suitable for fabricating the strap-like member . . . include synthetic polymeric materials which can be formed into high strength yarns,” including, for example, “ultrahigh molecular weight polyethylene” and “polyesters.” Pet. 30 (quoting Ex. 1005, 5:54–61) (emphases omitted). Petitioner further directs us to where Van Kampen teaches that “the strap-like element is preferably fabricated from yarns of [such] material[s],” and that “[b]raids or weaves of these yarns are preferred.” *Id.* (quoting Ex. 1005, 5:62–65) (alterations added). Petitioner contends that an ordinarily skilled artisan “would have understood that a component made up of braids or weaves has a ‘multifilament structure.’” *Id.* Petitioner also contends that an ordinarily skilled artisan “would have further understood from Van Kampen that any of the disclosed materials could have been used in the braid or weave, including polyethylene and polyester since these materials are commonly used in orthopedic implants.” *Id.* Petitioner relies on the declaration testimony of Dr. Jordan. *Id.* (citing Ex. 1002 ¶ 81); *see also id.* at 31–32 (citing Ex. 1002 ¶ 83). In his declaration, Dr. Jordan testifies that “[b]raided sutures consisting of both polyethylene and polyester[] . . . were known and commercially available before the priority date of the ’449 Patent,” and that an ordinarily skilled artisan “would have . . . known that sutures made up of a combination of polyethylene and polyester provided benefits such as

increased strength and resistance to fraying.” Ex. 1002 ¶ 83 (cited by Pet. 31–32).

Petitioner additionally directs us again to where Van Kampen teaches that “[f]astener 14 is implanted by drilling a hole in the femur 12,” and that legs of fastener 14 “are inserted through the braids of one end of augmentation device 10 and a small hole created in the biological tissue.” Pet. 32 (quoting Ex. 1005, 3:35–40). According to Petitioner, this “teaches attaching the reinforcement component directly to the first fastener to anchor it to the femur.” *Id.* As discussed above, Van Kampen’s fastener 14 corresponds to the recited first fastener, and Van Kampen’s femur 12 corresponds to the recited first bone. *See supra* Part III.C.2.a.ii.

Based on Petitioner’s argument and evidence, we are persuaded that Van Kampen teaches or suggests limitation 1.3. Patent Owner does not appear to separately dispute Petitioner’s analysis for this limitation. *See generally* PO Resp. To the extent that Patent Owner disputes Petitioner’s analysis in this regard, we discuss the parties’ arguments below with respect to claims 3 and 4. *See* PO Resp. 47 (asserting with respect to claims 3 and 4 that “Van Kampen does not describe a multifilament structure fabricated from a *combination* of polyethylene and polyester as required in element [1.3] of claim 1”).

v. Limitation 1.4: “securing a second fastener”

Claim 1 further recites “securing a second fastener at least partially within a second bone of a joint adjacent a second end of the ligament of the joint opposite the first end of the ligament.” For this limitation, which

Petitioner designates as limitation 1.4, Petitioner provides another annotated version of Figure 1 of Van Kampen, which is reproduced below. Pet. 32–33.

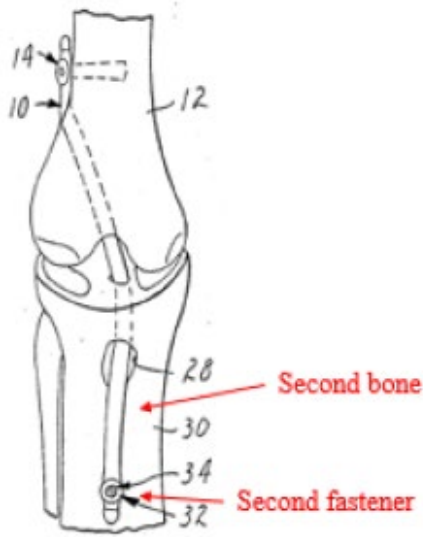


FIG. 1

Figure 1 of Van Kampen, as annotated by Petitioner, shows tissue augmentation device 10 implanted in a knee. *See* Ex. 1005, 3:17–19. As annotated Figure 1 shows, Petitioner identifies Van Kampen’s bushing 32 and screw 34 together as a “second fastener,” and Van Kampen’s tibia 30 as a “second bone.” Pet. 33; *see also id.* at 36.

To support its position, Petitioner directs us to where Van Kampen teaches that “[b]ushing 32 is implanted by inserting cylindrical portion 40 [of bushing 32] through the braids of one end of augmentation device 10 and a small hole created in the biological tissue (See FIG. 1) and then into a hole in the tibia,” and that “[s]crew 34 is then inserted into bushing 32 . . . and is bored into the tibia to securely affix augmentation device 10 to the tibia 30.” Pet. 33 (quoting Ex. 1005, 3:62–67). Petitioner additionally points to Van Kampen’s teaching that device 10 “augments the *entire length* of the tissue

and . . . is affixed to bone at each end.” *Id.* at 34 (quoting Ex. 1005, 7:36–41) (emphasis added by Petitioner). As discussed above, Van Kampen’s biological tissue, namely, the damaged ligament itself, corresponds to the recited ligament. Petitioner contends that an ordinarily skilled artisan thus “would have understood that Van Kampen’s second fastener would be placed ‘adjacent’ an end of the ligament.” *Id.*

Patent Owner disputes Petitioner’s analysis for limitation 1.4. PO Resp. 24–29. We address the parties’ arguments below.

vi. Limitation 1.5: “second end of the ligament”

In connection with the step of “securing a second fastener,” claim 1 further limits the recited second end of the ligament. Specifically, claim 1 recites “wherein the second end of the ligament is attached to the second bone of the joint before securing the second fastener.” For this limitation, which Petitioner designates as limitation 1.5, Petitioner relies again on Marshall and cross-references its discussion of limitation 1.2. Pet. 34. In that discussion, Petitioner points to Marshall as “disclos[ing] in more detail a method for repairing a ligament in which the first and second ends of a ligament are attached to first and second bones (the bones to which the damaged ligament was originally attached), or portions thereof are more securely attached if the original ligament is being used and intact.” Pet. 27 (citing Ex. 1006, 98–100). As discussed above, the damaged ligament that has been reapproximated in Van Kampen corresponds to the recited ligament, and the scenario where a ligament is reapproximated refers to ligament repair. *See supra* Part III.C.2.a.iii (citing Ex. 1002 ¶ 51).

Referring to Marshall's description of ligament repair in particular, Petitioner asserts that "the sutures are tied down after tensioning the ligament to its natural anatomic tension and attaching the ligament to the bone." Pet. 35. To illustrate, Figure 1 of Marshall is reproduced below.

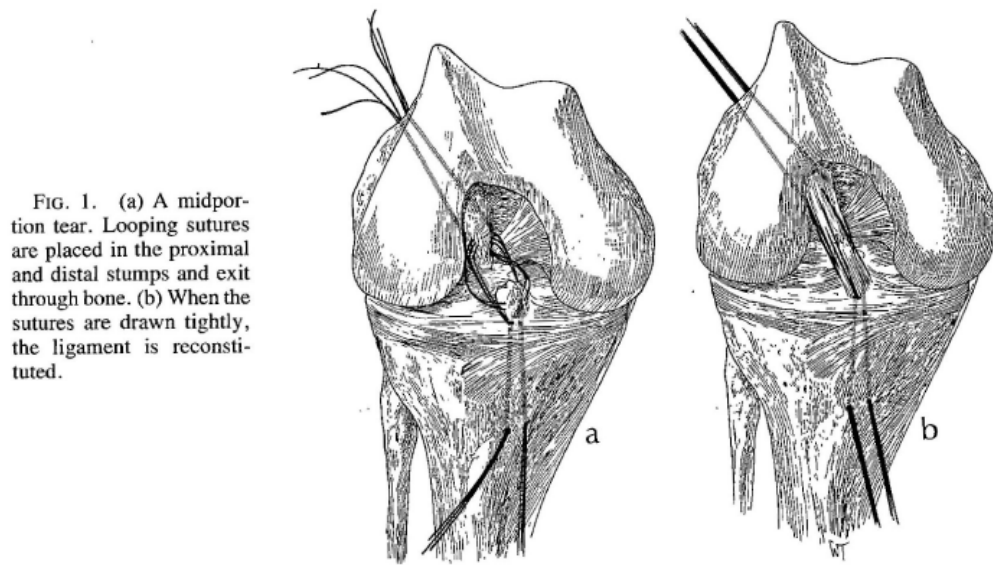


Figure 1 of Marshall shows a midportion tear in the ligament. Ex. 1006, 99. The left-hand view of Figure 1 shows looping sutures that are placed in proximal and distal stumps and exit through bone. *Id.* The right-hand view of Figure 1 shows that the ligament is reconstituted when the sutures are drawn tightly. *Id.*

Petitioner contends that "[t]he second fastener in Van Kampen is being used to attach an augmentation device for a repaired or reconstructed ligament, and therefore, a [person of ordinary skill in the art] would have appreciated that the fastener would have been secured in place after the ligament is repaired (including being attached)." Pet. 35. Petitioner adds that "the tissue augmentation device in Van Kampen 'is adapted for fixation at each end thereof to the anatomical structures connected by the ligament or tendon,' (Ex. 1005, 2:32–[3]4), which suggests that the ligament has already

been attached to the second bone before the second fastener is inserted.” *Id.* at 35.⁶ Petitioner relies on the declaration testimony of Dr. Jordan. *Id.* at 34–35 (citing Ex. 1002 ¶ 87).

Based on Petitioner’s argument and evidence, we are persuaded that Petitioner’s proposed combination of Van Kampen and Marshall teaches limitation 1.5 of claim 1. Patent Owner does not separately dispute Petitioner’s showing in this regard. *See generally* PO Resp.

As with limitation 1.2, however, Patent Owner disputes Petitioner’s proffered rationale for combining Van Kampen and Marshall. PO Resp. 29–46. We address the parties’ arguments below.

vii. Limitations 1.6, 1.7, and 1.8: “reinforcement component”

The final recitations of claim 1 further limit the reinforcement component discussed above (*see supra* Part III.C.2.a.iv). For example, in connection with the step of “securing a second fastener,” claim 1 recites “wherein the reinforcement component is attached to the second fastener to anchor the reinforcement component to the second bone.” For this limitation, which Petitioner designates as limitation 1.6, Petitioner directs us to where Van Kampen teaches that “[b]ushing 32 is implanted by inserting cylindrical portion 40 [of bushing 32] through the braids of one end of augmentation device 10 and a small hole created in the biological tissue (See FIG. 1) and then into a hole in the tibia,” and that “[s]crew 34 is then inserted into bushing 32 . . . and is bored into the tibia to securely affix

⁶ Petitioner cites “Ex. 1005, 2:32–24,” but this appears to be a typographical error. The quoted language appears at Exhibit 1005, column 2, lines 32 through 34.

augmentation device 10 to the tibia 30.” Pet. 37 (quoting Ex. 1005, 3:62–67). As discussed above, Van Kampen’s augmentation device 10 corresponds to the recited reinforcement component, Van Kampen’s bushing 32 and screw 34 together correspond to the recited second fastener, and tibia 30 corresponds to the recited second bone. *Id.* at 33, 36.

Claim 1 also recites “wherein the reinforcement component extends between the first and second ends of the ligament.” For this limitation, which Petitioner designates as limitation 1.7, Petitioner directs us again to where Van Kampen teaches that its device 10 “augments the *entire length* of the tissue and is affixed at both ends to the anatomical structures connected by the ligament or tendon being repaired or reconstructed,” that is, “in the case of ligament repair or reconstruction the device is affixed to bone at each end.” Pet. 39 (quoting Ex. 1005, 7:36–41) (emphasis added by Petitioner). As discussed above, device 10 has “a strap-like element which provides permanent augmentation of the tissue.” Ex. 1005, 5:22–25. Petitioner contends that “[b]ecause the Van Kampen strap-like element extends along the entire length of the ligament, a [person of ordinary skill in the art] would have understood that it extends between the first and second ends of that ligament.” Pet. 39. Petitioner relies on the declaration testimony of Dr. Jordan. *Id.* (citing Ex. 1002 ¶ 91).

Lastly, claim 1 recites “wherein the reinforcement component is tensioned directly between the first and second fasteners.” For this limitation, which Petitioner designates as limitation 1.8, Petitioner contends that “Van Kampen teaches that augmentation device 10 (the strap-like element) is directly attached to fastener 14 and to bushing 32/screw 34 (the first and second fasteners).” Pet. 39–40 (citing Ex. 1005, 3:35–47, 3:49–68).

As discussed above, Van Kampen teaches that the legs of fastener 14 are inserted through the braids of one end of augmentation device 10, and that the cylindrical portion of bushing 32 is inserted through the braids of the other end of augmentation device 10. Ex. 1005, 3:37–40, 3:62–65 (cited by Pet. 40).

Petitioner further contends that an ordinarily skilled artisan “would have understood from Van Kampen that the strap-like element is tensioned between the fasteners” because “the ends of the augmentation device are ‘securely affixed’ to the tibia and femur,” as discussed above, and “Van Kampen explains that the augmentation device supports the working loads normally supported by the ligament.” Pet. 40. Petitioner directs us to where Van Kampen teaches that the “strap-like element [is] formed of a stable biocompatible material having sufficient mechanical properties to support at least the working loads normally supported by the ligament.” Ex. 1005, 2:23–30 (cited by Pet. 40). Petitioner also points us to Van Kampen’s teaching that its augmentation device “provide[s] a temporary total prosthesis for the ligament.” *Id.* at 5:22–29 (cited by Pet. 40). According to Petitioner, an ordinarily skilled artisan “would have understood that the disclosed strap-like element would be tightened between the fasteners to act properly as a ‘total prosthesis,’” and that “[t]his is because healthy ligaments are in tension and for the strap-like element to supplement the natural anatomical function, it would need to be tightened to the damaged ligament’s natural anatomic tension.” Pet. 40–41. Petitioner adds that, “[o]therwise, it would not be supporting the load in a way that allows for the damaged ligament to heal.” *Id.* Petitioner relies on the declaration testimony of Dr. Jordan. *Id.* at 40–41 (citing Ex. 1002 ¶ 93); *see also id.* at

41 (citing Ex. 1002 ¶¶ 93, 95). On this record, Petitioner’s contention in this regard is consistent with Van Kampen’s teaching that “the strap-like element must have sufficient tensile strength to carry the working loads normally carried by the ligament . . . being repaired or reconstructed and low flexural rigidity so as to be flexible enough to prevent interference with the normal movement of the muscular or skeletal structures connected by the device.” Ex. 1005, 5:43–49 (cited by Pet. 40).

Based on Petitioner’s argument and evidence, we are persuaded that Van Kampen teaches limitations 1.6, 1.7, and 1.8. Patent Owner does not separately dispute Petitioner’s analysis for these limitations. *See generally* PO Resp.

viii. The Parties’ Disputes

Patent Owner makes several arguments, which we address in turn.

(A) Limitations 1.1 and 1.4: Securing First and Second Fasteners

Patent Owner argues that Van Kampen does not teach limitation 1.1, which requires “securing a first fastener at least partially *within a first bone* of a joint *adjacent a first end of a ligament* of the joint,” or limitation 1.4, which requires “securing a second fastener at least partially *within a second bone* of a joint *adjacent a second end of the ligament* of the joint opposite the first end of the ligament,” where specifically “[t]he emphasized portions . . . are missing from Van Kampen and Marshall.” PO Resp. 24.⁷ As

⁷ We note that Patent Owner does not discuss Marshall for this argument, focusing instead on Van Kampen. *See* PO Resp. 21–29.

support, Patent Owner provides an annotated version of Figure 1 of Van Kampen, which is reproduced below. *Id.* at 25.

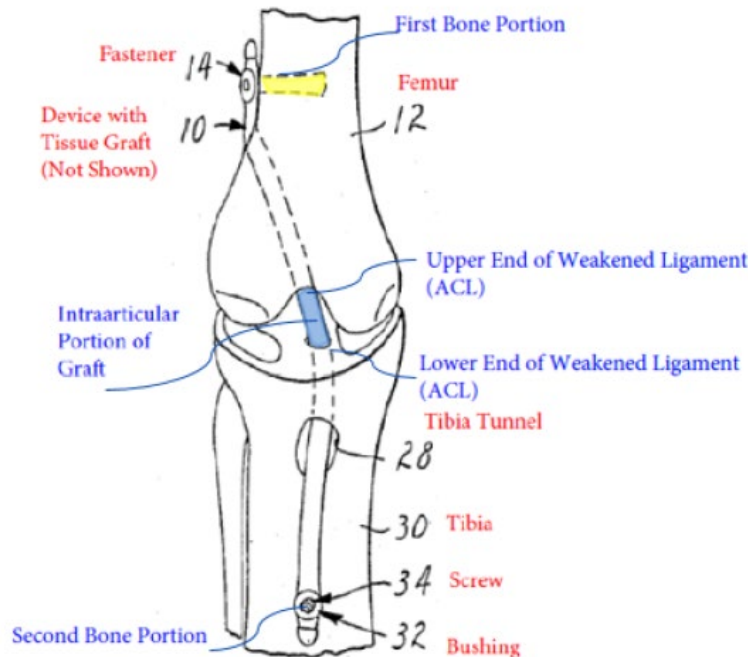


FIG. 1

Figure 1 of Van Kampen, as annotated by Patent Owner, shows a knee joint with augmentation device 10 in place. *See* Ex. 1005, 3:1–2, 3:18–19. Patent Owner contends that Van Kampen does not satisfy limitations 1.1 or 1.4 in either the context of ACL repair or the context of ACL reconstruction. PO Resp. 24–29. Patent Owner refers to its annotated version of Figure 1 of Van Kampen throughout its analysis.

With respect to ACL repair, Patent Owner asserts that “the damaged ACL is reapproximated by standard surgical techniques,” which “would repair the damaged natural ACL such that it would be intraarticular (within the joint) in the blue highlighted space shown in [annotated] FIG. 1” of Van Kampen. PO Resp. 24, 27. According to Patent Owner, annotated Figure 1

of Van Kampen shows that “fastener 14 is not secured *adjacent* a first end of the ACL (*i.e.*, at the top of the blue highlighted space),” and that “fastener 32/34 is not secured adjacent to the second end of the ACL (*i.e.*, at the bottom of the blue highlighted space).” *Id.* Patent Owner relies on the declaration testimony of Dr. Pedowitz. *Id.* at 24 (citing Ex. 2001 ¶ 57), 27 (citing Ex. 2001 ¶ 61); *see also id.* at 24–26 (citing Ex. 2001 ¶ 58), 27–28 (citing Ex. 2001 ¶ 62). In his declaration, Dr. Pedowitz testifies,

From FIG. 1 of Van Kampen, about half of the LAD [ligament augmentation device] device 10 is above and half is below the knee joint. It follows that the fastener 14 (or fastener 32/34) is approximately four inches away from the upper (or lower) end of the ACL. In my opinion, this distance is too great to be considered ‘adjacent’ to the anatomic origin of the ACL.

Ex. 2001 ¶ 58 (cited by Pet. 24–26). Dr. Pedowitz adds,

Of note, I personally used free tissue grafts and approaches surgically during my sports medicine fellowship (1993-1994), and I performed the procedure many times. So I can speak from personal experience about the operation[] With this surgical technique, the point of fixation on the lateral femur was not adjacent to the upper end of the native ACL. In my opinion, these geometries and distances are directly relevant to the procedure that is drawn in FIG. 1 of Van Kampen. The same is true of the tibial tunnel and its distance from the lower end of the native ACL.

Id.

With respect to ACL reconstruction, Patent Owner asserts that “the damaged ACL is replaced by a tissue graft.” PO Resp. 26, 28. Patent Owner further asserts that Figure 1 of Van Kampen shows that “fastener 14 is attached to the upper end of a free tissue graft used in the ACL reconstruction,” not “adjacent to the first end of the ACL (*i.e.*, at the top of the blue highlighted space).” *Id.* at 27. Patent Owner also asserts that

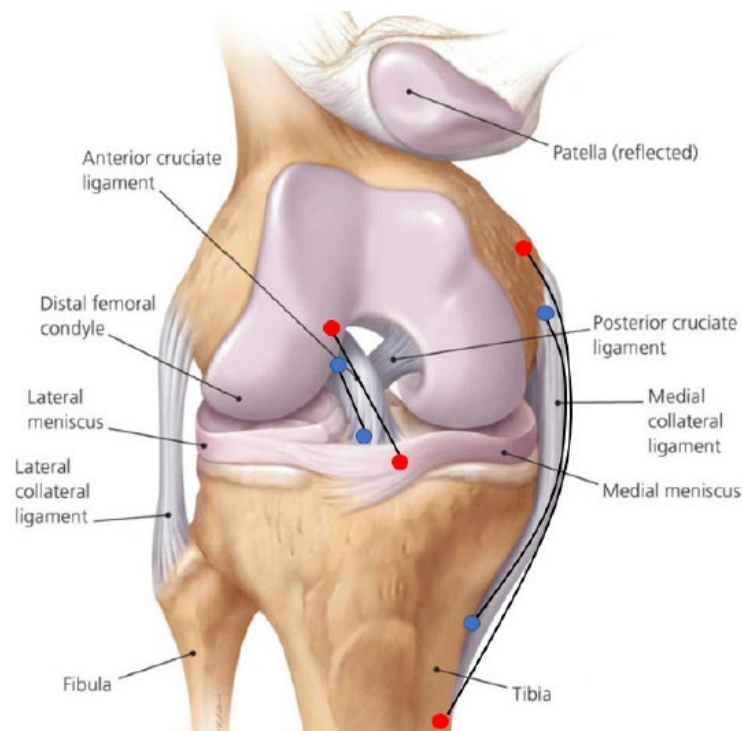
“fastener 32/34 is attached to the second end of a free tissue graft used in the ACL reconstruction,” not “adjacent to the second end of the ACL (*i.e.*, at the bottom of the blue highlighted space, in the region where the ACL inserts upon the proximal tibia within the knee joint).” *Id.* at 28. Patent Owner contends that “[t]he free tissue graft is not the weakened ACL, and securing the fastener to the free tissue graft is not securing the fastener to the weakened ACL.” *Id.* at 27, 28–29. Patent Owner relies on the declaration testimony of Dr. Pedowitz. *Id.* at 26–29 (citing Ex. 2001 ¶¶ 59, 63).

Petitioner responds that Patent Owner’s argument “relies on limiting Van Kampen to its description of ACL reconstruction exemplified in Figure 1, thereby ignoring the teachings elsewhere in the specification that support [Petitioner’s] conclusion.” Pet. Reply 2. Petitioner asserts that “Van Kampen describes that the first and second fasteners are placed through ‘a small hole placed in the biological tissue’ and the underlying bone, where the biological tissue can be ‘the damaged ligament or tendon itself.’” *Id.* at 2–3 (citing Ex. 1005, 3:35–47, 4:64–5:21). As support, Petitioner cross-references its Petition, which points to Van Kampen’s teaching that “[f]astener 14 is implanted by drilling a hole in the femur 12,” where “[l]egs 22 of the receiver 16 [of fastener 14] are inserted through the braids of one end of augmentation device 10 and a small hole created in the biological tissue,” and then “into the hole in the femur 12.” Pet. Reply 2 (citing Pet. 24–26, 32–34); Ex. 1005, 3:35–42 (cited by Pet. 24–25). The Petition also points to Van Kampen’s teaching that “[b]ushing 32 is implanted by inserting cylindrical portion 40 through the braids of one end of augmentation device 10 and a small hole created in the biological tissue . . . and then into a hole in the tibia.” Ex. 1005, 3:62–65 (cited by Pet. 33).

In addition, the Petition points to Van Kampen’s teaching that, “[i]n the case of ligament or tendon repair, the biological tissue used in conjunction with the device of the invention is the damaged ligament or tendon itself which has been reapproximated by standard surgical techniques.” *Id.* at 5:4–8 (cited by Pet. 25).

Petitioner further asserts that “Van Kampen explains that the device ‘augments the entire length of the tissue and is affixed at both ends to the anatomical structures connected by the ligament or tendon being repaired or reconstructed,’ and that “the device is used ‘in parallel’ and ‘adjacent to’ the ligament such that it shares ‘a common load’ with the ligament.” Pet. Reply 3 (citing Ex. 1005, 4:51–63, 7:37–39). As the Petition points out, Van Kampen explains in particular that its “augmentation device and the tissue are used *adjacent* to one another along their lengths,” and, “in the case of ligament repair or reconstruction the device is affixed to bone at each end.” Ex. 1005, 4:56–60, 7:40–41 (quoted by Pet. 25–26) (emphasis added by Petitioner). Van Kampen also explains that “[i]n no event is one end [of the device] affixed only to the tissue being augmented.” *Id.* at 7:44–46 (quoted by Pet. 25).

According to Petitioner, an ordinarily skilled artisan “would understand that [Van Kampen’s] fasteners are placed near the end[s] of the ligament being treated, either through the ligament and into the bone, or directly into bone, near the first and second ends of the ligament.” Pet. Reply 3. To illustrate, Petitioner provides a figure, which is reproduced below. *Id.* at 7.



Petitioner's figure illustrates various knee ligaments. *See* Ex. 1016 ¶ 3 (Dr. Jordan's Supplemental Declaration). Petitioner asserts that its figure shows that "one could place the fasteners of the Van Kampen augmentation device through the ends of the ACL ligament into the femur and the tibia (shown in blue), or directly into the femur and the tibia adjacent the ends of the ACL (shown in red)." Pet. Reply 7–8. Petitioner relies on the declaration testimony of Dr. Jordan. *Id.* (citing Ex. 1016 ¶ 3).

Petitioner additionally asserts that Patent Owner's declarant "Dr. Pedowitz also acknowledges that the fasteners of an augmentation device are able to be placed intra-articularly when an ACL ligament is being augmented." Pet. Reply 8. As support, Petitioner directs us to where Dr. Pedowitz testified during his deposition, "Well, for the ACL, by definition because the ACL is an intra-articular structure, so if we were going to place an anchor proximate, meaning very close to the anatomic

origin and insertion of an intra-articular structure, we would place those anchors intra-articular.” Ex. 1017, 88:16–20 (cited by Pet. Reply 8). Petitioner further directs us to a print copy of a webpage showing what Petitioner describes as “threaded anchors being used for intra-articular ACL repair.” Pet. Reply 8 n.1 (citing Ex. 2009).

Patent Owner counters that Petitioner relies on the description of Figure 1 of Van Kampen “to incorrectly assert that the fastener is secured adjacent to the ends of the ligament.” PO Sur-reply 2 (citing Pet. 24–26, 32–34). Patent Owner asserts that Van Kampen’s “device 10 shown in FIG. 1 ‘has a tissue graft (not shown) sutured along its length,’” which means that “[t]he ‘small hole created in the biological tissue’ for fastener 14 and bushing 32 is a hole in the *tissue graft*, not the damaged ligament itself.” *Id.* at 2–3. Referring still to Figure 1 of Van Kampen, Patent Owner adds that “the ACL is intra-articular . . . and the fastener 14 and bushing 32 are nowhere near the ACL.” *Id.* at 3; *see also id.* at 8 (“[T]he fastener of FIG. 1 is not secured into bone adjacent the ends of the ACL.”). According to Patent Owner, an ordinarily skilled artisan “would *not* have understood from [Van Kampen’s teachings] that the fasteners are placed through the ligament and into bone, or directly into bone near the ends of the ligament (in the intraarticular space of the joint for the ACL).” *Id.* at 4; *see also id.* at 5 (“It follows that a [person of ordinary skill in the art] would *not* have understood from [Van Kampen’s teachings] that the fasteners are placed through the ends of ligaments or adjacent to the ends of the ligament.”); *id.* at 7–8 (“The general references in Van Kampen to placing the device ‘in parallel’ to the tissue relied upon by Petitioner concern a tissue graft and do not constitute a disclosure of placing the device through the ends of the ligament.”).

Patent Owner further asserts that although “Petitioner contends that a [person of ordinary skill in the art] would have understood that one *could* place the fasteners of Van Kampen’s augmentation device through the ends of the ACL into the femur and tibia,” Petitioner’s “argument fails both because it is a new untimely argument raised for the first time in Reply and because it is factually incorrect.” PO Sur-reply 7; *see also id.* at 8 (“Petitioner now introduces new Declaration testimony from Dr. Jordan asserting that a [person of ordinary skill in the art] would have understood that the fasteners *could* have been placed in the locations shown in [Petitioner’s] new image,” which “is improper [testimony] as it is unsupported hindsight analysis and is a new argument improperly raised for the first time in Reply.”) (citing Pet. Reply 7–8). Patent Owner reiterates that “there is no teaching or suggestion in Van Kampen to place the fasteners of Van Kampen’s augmentation device through a ligament and into bone or into bone adjacent to the ends of the ligament such as the ACL.” *Id.* at 7. Patent Owner adds that Petitioner “provides no explanation as to why the fasteners/bushings of the Van Kampen device would be placed differently for an ACL repair than for an ACL reconstruction.” *Id.* at 6; *see also id.* at 8 (“Petitioner also provides no argument or motivation for a [person of ordinary skill in the art] to make a combination with these new changed fastener locations.”).

Additionally, Patent Owner asserts that “Petitioner cites Dr. Pedowitz’s testimony *about the disclosure of the ’449 Patent and its FIGS. 11A-11C* as acknowledgement ‘that fasteners of an augmentation device are able to be placed intra-articularly’ either ‘through the native ACL [or MCL] tissue, or adjacent to the end of the ligament.’” PO Sur-reply 8–9.

Patent Owner further asserts that “Petitioner also cites Exhibit 2009, which published in 2017 well after the time of the invention as showing threaded anchors used for intra-articular ACL repair.” *Id.* at 9. According to Patent Owner, “[r]elying on the teachings in the ’449 Patent itself or teachings in references well after the time of the invention is the epitome of an improper hindsight reconstruction.” *Id.*

Patent Owner’s argument and evidence do not defeat Petitioner’s showing for claim limitations 1.1 and 1.4. The parties agree that Figure 1 of Van Kampen illustrates a knee joint with an augmentation device in place, in the context of an ACL *reconstruction* (as opposed to an ACL *repair*). Pet. Reply 2 (referring to “description of ACL reconstruction exemplified in Figure 1” of Van Kampen); PO Sur-reply 3 (referring to “the ACL reconstruction shown in FIG. 1” of Van Kampen); *see also* Ex. 1005, 3:1–2, 3:17–20 (“Device 10 has a tissue graft (not shown) sutured along its length.”). Van Kampen makes clear, however, that its augmentation device “is designed to be used in parallel with biological tissue for the repair or reconstruction of a ligament or tendon,” not just the reconstruction of a ligament or tendon. Ex. 1005, 4:51–53 (emphasis added) (cited by Pet. 25). Accordingly, Van Kampen’s teachings are not limited to what is shown in Figure 1. Nor does Petitioner rely solely on what is shown in Figure 1 to support its analysis.

As the parties acknowledge, Figure 1 of Van Kampen shows augmentation device 10 affixed at one end to femur 12 by fastener 14 and at the other end to tibia 30 by bushing 32 and screw 34. Ex. 1005, Fig. 1. Van Kampen explains that the augmentation device in Figure 1 is sutured to a *tissue graft* (i.e., not the ACL itself) along its length. *Id.* at 3:19–20 (cited

by PO Sur-reply 27); *see also id.* at 4:58–60 (“Preferably, the augmentation device is sutured or otherwise secured to the tissue along its length.”) (cited by Pet. 25). Van Kampen further explains that fastener 14 is inserted through one end of augmentation device 10 as well as a small hole in one end of the tissue (i.e., tissue graft), and then through a hole in femur 12. *Id.* at 3:34–41, Fig. 1 (cited by Pet. 24–25). Similarly, bushing 32 is inserted through the other end of augmentation device 10 as well as a small hole in the other end of the tissue, and then through a hole in tibia 30. *Id.* at 3:62–65, Fig. 1 (cited by Pet. 33). We agree with Patent Owner that fastener 14 and bushing 32 are not inserted through the ACL itself in Figure 1.

Figure 1, however, illustrates a case of ligament *reconstruction*, where the biological tissue used in conjunction with augmentation device 10 is a *tissue graft*. *See id.* at 4:64–5:8. As Petitioner points out, Van Kampen further teaches that, “[i]n the case of ligament or tendon *repair*, the biological tissue used in conjunction with the device of the invention is the *damaged ligament or tendon itself* which has been reapproximated by standard surgical techniques.” *Id.* at 5:4–8 (emphases added) (cited by Pet. 25, 33). That is, in the case of a ligament repair, the biological tissue is the ACL itself. Petitioner points us to where Van Kampen also teaches that “[t]he augmentation device and the tissue are used adjacent to one another along their lengths,” and that “the [augmentation] device is affixed to bone at each end.” *Id.* at 4:56–58, 7:36–44 (quoted by Pet. 25–26). These additional teachings in Van Kampen are key to Petitioner’s analysis.

In light of these cited teachings in Van Kampen, we are persuaded that Van Kampen teaches or suggests inserting fastener 14 through one end of augmentation device 10 and one end of a damaged ligament (i.e., ACL),

and then into femur 12, *in the context of ligament repair*. We also are persuaded that Van Kampen teaches or suggests inserting bushing 32 through the other end of augmentation device 10 and the other end of the damaged ligament, and then into tibia 30, *in the context of ligament repair*. Because Van Kampen’s fastener and bushing are inserted through respective ends of the augmentation device and damaged ligament, and then into respective bones, the fastener and bushing are secured to the ends of the ligament itself and thus to bones adjacent to the ends of the ligament.⁸ Accordingly, contrary to Patent Owner’s position, we are persuaded that Van Kampen teaches claim limitation 1.1, which requires “securing a first fastener at least partially *within a first bone* of a joint *adjacent a first end of a ligament* of the joint,” as well as claim limitation 1.4, which requires “securing a second fastener at least partially *within a second bone* of a joint *adjacent a second end of the ligament* of the joint opposite the first end of the ligament.” See PO Resp. 24.

Moreover, Van Kampen teaches that “[i]n no event is one end [of the augmentation device] affixed only to the tissue being augmented.” Ex. 1005, 7:44–46 (cited by Pet. 25). As Van Kampen explains that both *ends* of the augmentation device are affixed to bone (*id.* at 7:40–41), this additional teaching in Van Kampen (i.e., that the *ends* of the augmentation

⁸ By contrast, in the context of ligament *reconstruction*, Van Kampen’s fastener and bushing are inserted through respective ends of the augmentation device and *tissue graft* (i.e., not the damaged ligament itself), and then into respective bones. See Ex. 1005, 3:34–41, 3:62–65, Fig. 1. As discussed above, Patent Owner’s declarant Dr. Pedowitz opines that the fixation sites in a ligament *reconstruction* are not adjacent to the ends of the *ligament*. Ex. 2001 ¶ 58 (citing Ex. 1005, Fig. 1).

device cannot be affixed only to the tissue) contemplates *affixing the ends* of the augmentation device *to both the tissue and bone*. In other words, contrary to Patent Owner's position, Van Kampen contemplates placing its fasteners through the ends of the augmentation device and through the ends of the ligament and into bone adjacent to the ends of the ligament. *See* PO Sur-reply 7 (“[T]here is no teaching or suggestion in Van Kampen to place the fasteners of Van Kampen's augmentation device through a ligament and into bone or into bone adjacent to the ends of the ligament such as the ACL.”).

We note Patent Owner's contention that “[t]he Petition relies upon Van Kampen's FIG. 1 for claim elements [1.1], [1.3]-[1.4] and [1.6]-[1.8],” and, “[t]hus, Van Kampen's general teachings of a ligament are not what the Petition relied upon in making its alleged case for obviousness and it is improper for Petitioner to make this new argument in any event.” PO Sur-reply 6. As discussed above, however, Petitioner does not rely solely on Figure 1 of Van Kampen to support its analysis in the Petition. For example, Petitioner relies on Van Kampen's teaching in the specification that, “[i]n the case of ligament or tendon repair, the biological tissue used in conjunction with the device of the invention is the damaged ligament or tendon itself which has been reapproximated by standard surgical techniques.” Ex. 1005, 5:4–8 (cited by Pet. 25, 33). This additional teaching supports Petitioner's analysis for claim limitations 1.1 and 1.4.

(B) Teaching Away from Primary Repair

Patent Owner asserts that Petitioner's declarant “Dr. Jordan opines that a [person of ordinary skill in the art] would have found it obvious to use

the methods and device disclosed in Van Kampen to augment a ligament such as the ACL, which has been reapproximated using the technique described in Marshall,” and “would have had a reasonable expectation of success in using Van Kampen’s augmentation methods and devices with a reapproximated ACL using Marshall’s primary repair method ‘because such ACL repair was widely practiced in the field before the filing date of the ‘449 Patent.’” PO Resp. 29–30. According to Patent Owner, “[t]his is not correct.” *Id.* at 30. Patent Owner reasons that an ordinarily skilled artisan “would have known that ACL primary repairs, including Marshall’s ACL primary repair method, had been abandoned in the art.” *Id.* at 31.

As support, Patent Owner points to a print copy of a webpage from Petitioner’s website that states that “the technique of primary ACL repair was largely abandoned by the mid-1990’s due to marginal clinical outcomes.” Ex. 2009, 1 (cited by PO Resp. 31). Patent Owner also points to a 1990 paper in which the authors say, “It is doubtful to us that [repair] surgery in its present form will ever prove successful, and therefore, we are justified to consider tendon transfer or appropriate synthetic substitution.” Ex. 2010, 234 (cited by PO Resp. 32–33). In addition, Patent Owner points to a 2015 paper that reviewed past studies with similar findings, which the paper says “delivered the deathblow to primary repair of the ACL.” Ex. 2012, 2233 (cited by PO Resp. 33–34). Patent Owner further points to another 2015 paper stating that “[t]he discussion of primary repair of the ACL became more mainstream in the 1970s,” but “inconsistent midterm results of such repairs[] steered the field in the direction of augmentation and, eventually, reconstruction.” Ex. 2011, 2162 (cited by PO Resp. 34–35). Lastly, Patent Owner points to a 2007 book by its declarant Dr. Pedowitz

stating that “[p]rimary repair has been abandoned due to high failure rates.” Ex. 2004, 580 (cited by PO Resp. 34), 556. In making that statement, the book cites a 1993 publication. *Id.* at 580, 594.

Patent Owner concludes that “[t]he prior art strongly teaches away from using primary ACL repair due to poor clinical outcomes,” and that an ordinarily skilled artisan “would not have been motivated to reapproximate the ACL with a primary repair method, including Marshall’s primary repair method, since primary repair had been abandoned by orthopedic surgeons by that time.” PO Resp. 31, 35; *see also id.* at 35–37 (“A [person of ordinary skill in the art] would have been motivated to perform ACL reconstruction, not ACL primary repair.”).

Petitioner responds that “Van Kampen states that its augmentation device can be used alongside a damaged ligament or tendon ‘which has been reapproximated by standard surgical techniques,’” and that “[Petitioner’s declarant] Dr. Jordan and [Patent Owner’s declarant] Dr. Pedowitz agree that the Marshall technique for ACL repair was widely known by a [person of ordinary skill in the art] at the time Van Kampen was filed.” Pet. Reply 9 (citing Ex. 1002 ¶ 68; Ex. 1005, 5:4–8; Ex. 1017, 82:5–17). Petitioner asserts that “it is undeniable that the combination of Van Kampen and Marshall suggest augmentation of a repaired ACL, thereby rendering the claims obvious.” *Id.* at 11.

Petitioner further asserts that “[t]he fact that some of the publications cited by [Patent Owner] suggest that ACL reconstruction was a ‘preferred’ option in some scenarios does not amount to ‘teaching away.’” Pet. Reply 10. Petitioner points to the 1990 paper cited by Patent Owner. *Id.* at 11 (citing Ex. 2010). Petitioner observes that, “in this study, 75% of ACL

repair patients (24 of 32) reported satisfactory or excellent functional ratings after ACL repair . . . , and several patients indicated that th[ey] had no adverse reaction or symptoms after 5 years or more.” *Id.* at 11–12 (citing Ex. 2010, 234). According to Petitioner, “[t]his is hardly the ‘clear discouragement’ in the prior art required to teach away from ACL repair.” *Id.* at 12.

Additionally, Petitioner asserts that “[t]he remainder of the publications cited by [Patent Owner] also fail to teach away as each identifies successful outcomes of ACL repairs for at least a subset of patients, and/or confirms that ACL repairs, and studies on ACL repairs, were in fact being conducted at the relevant time.” Pet. Reply 12. As an example, Petitioner points to the 2015 paper cited by Patent Owner that reviewed past studies. *Id.* at 12–13 (citing Ex. 2012). That paper concluded that “a subset of patients achieved acceptable long-term results,” and that “[p]rimary repair of the ACL may be an effective treatment modality for an appropriately selected subset of patients.” Ex. 2012, 2233 (cited by Pet. Reply 12–13). Petitioner also points to Patent Owner’s declarant Dr. Pedowitz’s deposition testimony, where he agreed that the 2015 paper “found ACL repair to be successful for at least some subset of patients,” and explained that “[i]n the analysis they tried to parse out whether there was some subgroup[] that might have done better than the others in terms of ACL repair.” Ex. 1018, 21:20–25 (cited by Pet. Reply 13).

Patent Owner counters that the 2015 paper cites eight clinical studies, where “four were long-term follow up studies from ACL repairs done in the 1970s and 1980s, and four others were studies after 2004 of ACL repair in skeletally immature children.” PO Sur-reply 12 (citing Ex. 2012, 2234–

2235). Patent Owner adds that the 2015 paper “is a non-prior art study, and its conclusions in 2015 — 11 years after the time of the invention — were unknown and unrecognized in 2004 and are therefore irrelevant to obviousness.” *Id.* at 13. With respect to the 1990 paper, Patent Owner asserts that Petitioner “ignores” the Comment section following the paper, which states that “primary repair was not successful and other forms of reconstruction should be pursued which is the prevailing thinking today [1990].” *Id.* at 14 (emphasis omitted) (quoting Ex. 2010, 236). According to Patent Owner, “[t]his is, contrary to Petitioner’s characterizations, exactly the type of ‘clear discouragement’ in the prior art contemplated in the case law.” *Id.*

We disagree with Patent Owner. Although prior art may teach away if it criticizes, discredits, or otherwise discourages the solution claimed, we find that the references cited by Patent Owner do not teach away from ligament repair in all circumstances. *See In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004). As Petitioner points out, for example, the 2015 paper cited by Patent Owner concludes that “a subset of patients achieved acceptable long-term results.” Ex. 2012, 2233 (cited by Pet. Reply 12–13). The Discussion section of the 2015 paper states that “[h]istorical clinical data suggest that open primary repair of the ACL has an unacceptably high failure rate,” but, “[o]n second review, however, it is clear that a subset of patients in these *same studies* did meet the criteria for clinical success.” *Id.* at 2244 (emphasis added). That statement is based in part on “[o]ne of the landmark studies on primary ACL repair that supported the transition from primary repair to ACL reconstruction.” *Id.* at 2245. The 2015 paper explains that “[a]lthough [the landmark study’s] overall outcomes were

considered unacceptable and contributed to the widespread abandonment of ACL repair, it should be noted that a subset of patients did achieve excellent outcomes with this approach.” *Id.* The landmark study was published in 1991. *Id.* at 2247.

We note Patent Owner’s contention that the 2015 paper “is a non-prior art study, and its conclusions in 2015 — 11 years after the time of the invention — were unknown and unrecognized in 2004 and are therefore irrelevant to obviousness.” PO Sur-reply 13. Patent Owner’s contention, however, does not undermine Petitioner’s showing. Our reviewing court has explained that “[a] reference . . . must [be] considered for all it taught, disclosures that diverged and taught away from the invention at hand as well as disclosures that pointed towards and taught the invention at hand.”

Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 296 (Fed. Circ. 1985). Even though the conclusions in the 2015 paper were published after the time of the invention, we find that an ordinarily skilled artisan looking at the *same studies* (including the 1991 landmark study) at the time of the invention would have reached the same conclusions in the 2015 paper. Patent Owner does not argue otherwise. Indeed, the 2015 paper states it is “clear” that a subset of patients in the “same studies” met the criteria for clinical success. Ex. 2012, 2244.

This also can be seen from data in the 1990 paper cited by Patent Owner, which show that 75% of ACL repair patients reported satisfactory or excellent functional ratings after ACL repair, and that five patients indicated no adverse reaction or symptoms after five years or more. Ex. 2010, 234 (cited by Pet. Reply 11–12).

In sum, Van Kampen explicitly teaches that its augmentation device “is designed to be used in parallel with biological tissue for the repair or reconstruction of a ligament or tendon,” where, “[i]n the case of ligament or tendon *repair*, the biological tissue used in conjunction with the device of the invention is the *damaged ligament* or tendon itself which has been reapproximated by standard surgical techniques.” Ex. 1005, 4:51–53, 5:4–8 (cited by Pet. 25). Marshall describes a detailed method for repairing a ligament. Ex. 1006, 98–100 (cited by Pet. 27). And, studies conducted before the ’449 patent show that, “[a]lthough long-term human studies suggest collectively unacceptable outcomes for open primary repair of the ACL, a subset of patients achieved acceptable long-term results.” Ex. 2012, 2233 (cited by Pet. Reply 12–13); *see also id.* at 2245 (“Although their overall outcomes [in the 1991 landmark study] were considered unacceptable and contributed to the widespread abandonment of ACL repair, it should be noted that a subset of patients did achieve excellent outcomes with this approach.”); Ex. 2010, 234. Patent Owner’s teaching away argument thus does not defeat Petitioner’s showing for claim 1 of the ’449 patent.

Based on the record before us, we are persuaded that Petitioner’s proffered reasoning for combining the teachings of Van Kampen and Marshall is sufficient to support the legal conclusion of obviousness. *See In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (“[T]here must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”); Ex. 1005, 5:4–8 (“[T]he biological tissue used in conjunction with the device . . . is the damaged ligament or tendon itself which has been reapproximated by standard surgical techniques.”); Ex. 1002

¶ 51 (“[A] scenario wherein the native tissue is reapproximated is typically referred to as ligament ‘repair.’”); Pet. 27 (“Marshall discloses in more detail a method for repairing a ligament in which the first and second ends of a ligament are attached to first and second bones (the bones to which the damaged ligament was originally attached), or portions thereof are more securely attached if the original ligament is being used and intact.”).

(C) Synthetic LAD in ACL Augmentation

Patent Owner argues that an ordinarily skilled artisan “would not have used ACL primary repair methods with or without an LAD [ligament augmentation device] because ACL primary repair had been abandoned in orthopedic surgical practice in the mid-1990’s,” and that an ordinarily skilled artisan therefore “would not have had reason to combine augmentation with Van Kampen’s synthetic LAD with Marshall’s ACL primary repair.” PO Resp. 40. Patent Owner adds that a “systematic review of LAD use . . . also concluded that ‘in clinical situations *no significant advantages have been observed with the use of LAD* . . . in the acute setting *to augment repair* of the torn ACL.’” *Id.* (emphases added by Patent Owner) (quoting Ex. 2013, 422). According to Patent Owner, “[g]iven the abandonment of ACL primary repair and evidence of synthetic LADs providing no significant advantage when used with ACL primary repair, a [person of ordinary skill in the art] would not have had a reasonable expectation of success in this Van Kampen/Marshall combination.” *Id.*

We disagree. As discussed above, we find that Patent Owner’s cited references do not teach away from using ligament repair, at least for a subset of patients. *See supra* Part III.C.2.a.viii.(B). Additionally, Van Kampen

explicitly teaches that its augmentation device “is designed to be used in parallel with biological tissue for the repair or reconstruction of a ligament or tendon.” Ex. 1005, 4:51–53 (cited by Pet. 25). That using a LAD (e.g., Van Kampen’s augmentation device) to augment an ACL repair may not have provided “significant advantages” does not take away from this explicit teaching in Van Kampen. *See Intel Corp. v. PACT XPP Schweiz AG*, 61 F.4th 1373, 1381 (Fed. Cir. 2023) (explaining that the petitioner need only show that the proposed combination would have provided a “suitable option”). Accordingly, Patent Owner’s argument does not undermine Petitioner’s obviousness showing.

(D) ACL Reconstruction

Patent Owner “addresses whether a [person of ordinary skill in the art] would have augmented ACL reconstruction with a synthetic LAD at the time of the invention, *even though Petitioner’s obviousness rationale does not include ACL reconstruction.*” PO Resp. 41–46 (emphasis added). Additionally, Patent Owner argues that, “[e]ven if Petitioner had combined Van Kampen’s augmentation methods and devices with Marshall’s quadriceps tendon substitution (QTS) ACL reconstruction method (*which Petitioner did not assert in its Petition*), Marshall’s reconstruction method does not secure a second fastener . . . as required in element[] [1.4] of claim 1 of the ‘449 Patent.” *Id.* at 37 (emphasis added). Patent Owner adds that an ordinarily skilled artisan “would have known that Marshall’s QTS reconstruction method was abandoned by practicing orthopedic surgeons by the time of the invention.” *Id.* at 38–39.

Patent Owner's arguments regarding ACL *reconstruction* do not address Petitioner's asserted ground of obviousness over Van Kampen and Marshall, which focuses on ACL *repair*. As Patent Owner acknowledges, "Petitioner's obviousness rationale does not include ACL reconstruction." PO Resp. 41. Accordingly, Patent Owner's arguments regarding ACL reconstruction are unavailing.

For the reasons given above, we are persuaded by Petitioner's argument and evidence that the proposed combination of Van Kampen and Marshall teaches or suggests all the limitations of claim 1. We also are persuaded that Petitioner's proffered reasoning for combining the teachings of Van Kampen and Marshall support the legal conclusion of obviousness.

b. Dependent Claim 2

Claim 2 depends from claim 1 and recites "the reinforcement component extends along the length of the ligament." For this limitation, Petitioner directs us to where Van Kampen teaches that its device is used "in parallel with biological tissue in the repair or reconstruction of ligaments and tendons," and "augments the *entire length* of the tissue and is affixed at both ends to the anatomical structures connected by the ligament or tendon being repaired or reconstructed." Pet. 42 (quoting Ex. 1005, code (57), 7:36–50).

Based on Petitioner's argument and evidence, we are persuaded that Van Kampen teaches the limitation of claim 2. Patent Owner does not separately dispute Petitioner's analysis for this limitation. See PO Resp. 46–47.

c. Dependent Claims 3 and 4

Claim 3 depends from claim 1 and recites “the reinforcement component comprises a suture.” Claim 4 depends from claim 3 and recites “the reinforcement component comprises a plurality of sutures.” Petitioner relies on the same discussion for both claims. *See* Pet. 45 (“For the reasons described . . . for claim 3, Van Kampen discloses [claim 4].”).

Petitioner asserts that “Van Kampen explains that the strap-like element of augmentation device 10 may ‘consist[] of an integral length of braid,’” and that it “may be fabricated from ‘polyolefins such as polypropylene, ultrahigh molecular weight polyethylene, and polybutylene; polyesters such as polyester terephthalate; polytetrafluoroethylene; and polyaramid,’ preferably fabricated from braids or weaves of yarns made of these materials.” Pet. 42–43 (citing Ex. 1005, 4:1–2, 5:54–65). Petitioner further asserts that, “[i]n the field of orthopedic surgery, this was suture material that was available and widely used in the relevant timeframe, and therefore a [person of ordinary skill in the art] would have understood the disclosed strap-like element is made of suture material.” *Id.* at 43. Petitioner relies on the declaration testimony of Dr. Jordan. *Id.* (citing Ex. 1002 ¶ 97).

Petitioner additionally asserts that “Van Kampen also explains that ‘the term ‘strap-like’ is used broadly to connote flexibility, and although the preferred embodiment is flat in cross-section, any cross-sectional geometry may be used.” Pet. 43 (citing Ex. 1005, 5:33–36). According to Petitioner, an ordinarily skilled artisan “would have further understood that [Van Kampen’s] strap-like element functioned as a suture to keep two surfaces in apposition of each other.” Pet. 43 (citing Ex. 1005, 5:33–36). Petitioner

asserts that “[i]t was well known in the field of orthopedic surgery that a suture is the material with which two surfaces are kept in apposition,” and that “[c]ommerically available sutures in the relevant timeframe served this purpose.” *Id.* Petitioner also asserts that an ordinarily skilled artisan “would have further understood that suture comes in different cross-sectional geometries,” and that “[s]utures with different cross-sectional areas were commercially available at the time of filing the ’449 Patent.” *Id.* Petitioner concludes that an ordinarily skilled artisan “would have understood [Van Kampen’s] strap-like element to be type of suture.” *Id.* Petitioner relies on the declaration testimony of Dr. Jordan. *Id.* (citing Ex. 1002 ¶ 98).

Under an alternative theory, Petitioner asserts that “Van Kampen also discloses an alternate embodiment shown in Figures 5 and 6, wherein the ligament augmentation device (44) is constructed of two strap-like elements (46 and 48) constructed from bundles of polypropylene filaments that are overlapped and sewn together using biodegradable suture 50.” Pet. 44 (citing Ex. 1005, 4:1–11, 8:16–38). Petitioner contends that an ordinarily skilled artisan “would have understood that this alternate embodiment discloses a reinforcement component that comprises a suture through its disclosure of suture 50, or either of the strap-like elements 46 and 48.” *Id.* With respect to claim 4 in particular, Petitioner adds that an ordinarily skilled artisan “would have understood that the embodiment shown in Figures 5 and 6 discloses or renders obvious a reinforcement component comprising a plurality of sutures through its disclosure of the multiple stitches of suture 50, or the combination of any of suture (50) and the two strap-like elements (46 and 48).” *Id.* at 45. Petitioner relies on the

declaration testimony of Dr. Jordan. *Id.* at 44–45 (citing Ex. 1002 ¶¶ 99–100).

Patent Owner responds that “Van Kampen does not describe a multifilament structure fabricated from a *combination* of polyethylene and polyester as required in element [1.3] of claim 1.” PO Resp. 47; *see also* PO Sur-reply 21.

Petitioner counters that Patent Owner’s declarant “Dr. Pedowitz admits that Van Kampen discloses a reinforcement component comprised of a multifilament structure, and discloses both polyester and polyethylene as suitable materials for the device.” Pet. Reply 22 (citing Ex. 1018, 38:5–39:6). Petitioner also asserts that its Petition “described in detail why a [person of ordinary skill in the art] would have used a combination of these materials, including that the combination provided benefits such as increased strength and resistance to fraying.” *Id.* (citing Pet. 30–32). Petitioner adds that “Dr. Jordan has explained, and Dr. Pedowitz does not refute, that braided sutures consisting of both polyethylene and polyester were known and commercially available before the priority date of the ’449 Patent.” *Id.* (citing Pet. 30–32).

As discussed above with respect to claim limitation 1.3, we are persuaded that Van Kampen teaches or suggests that the strap-like member of its augmentation device comprises a multifilament structure fabricated from polyethylene and polyester. *See supra* Part III.C.2.a.iv. Van Kampen teaches in particular that “[m]aterials which are suitable for fabricating the strap-like member . . . generally include synthetic polymeric materials which can be formed into high strength yarns,” such as “ultra high molecular weight polyethylene” and “polyesters.” Ex. 1005, 5:54–61 (cited by

Pet. 30). Van Kampen also teaches that “the strap-like element is preferably fabricated from *yarns* of the foregoing material,” where “[b]raids or weaves of these yarns are preferred.” *Id.* at 5:62–65 (cited by Pet. 30). We find that this description of the strap-like member in Van Kampen teaches or suggests a multifilament structure made from polyethylene and polyester.

Even if we were to find that Van Kampen’s cited description does not teach or suggest a multifilament structure made from polyethylene and polyester, we note Petitioner’s contention that an ordinarily skilled artisan “would have . . . known that sutures made up of a combination of polyethylene and polyester provided benefits such as increased strength and resistance to fraying.” Pet. 31 (citing Ex. 1002 ¶ 83). Patent Owner does not argue to the contrary. We find that Petitioner’s proffered reasoning for modifying Van Kampen’s augmentation device to provide a strap-like member made of polyethylene and polyester is sufficient to support the legal conclusion of obviousness.

Patent Owner does not otherwise dispute Petitioner’s analysis for claims 3 and 4. PO Resp. 47. On this record, we are persuaded that Petitioner’s argument and evidence teaches the limitations of claims 3 and 4.

d. Dependent Claim 6

Claim 6 depends from claim 1 and recites “the first and second bones and the joint are part of a knee.” For this limitation, Petitioner asserts that “[t]he augmentation device shown in Van Kampen Figure 1 depicts a knee joint including femur 12 and tibia 30.” Pet. 45. As support, Petitioner directs us to where Van Kampen teaches that “a braided tissue augmentation device 10 . . . is shown implanted in a knee,” where “[d]evice 10 is affixed

to the femur 12 by an expandable fastener 14” and “to the tibia 30 by bushing 32 and screw 34.” *Id.* at 45–46 (citing Ex. 1005, 3:17–23, 3:47–51).

Based on Petitioner’s argument and evidence, we are persuaded that Van Kampen teaches the limitation of claim 6. Patent Owner does not separately dispute Petitioner’s analysis for this limitation. PO Resp. 46–47.

3. Summary

In view of the foregoing, we determine that Petitioner has demonstrated by a preponderance of the evidence that claims 1–4 and 6 would have been obvious over Van Kampen and Marshall.

D. Obviousness over Van Kampen, Marshall, and Boyce

Petitioner asserts that claims 5 and 7–11 of the ’449 patent would have been obvious over Van Kampen, Marshall, and Boyce. Pet. 57–64. Patent Owner opposes. PO Resp. 50–53. For the reasons explained below, we determine that Petitioner has demonstrated by a preponderance of the evidence that claims 5 and 7–11 would have been obvious over Van Kampen, Marshall, and Boyce.

We provided an overview of Van Kampen and Marshall above. *See supra* Part III.C.1. Before addressing the parties’ arguments, we additionally provide an overview of Boyce.

1. Overview of Boyce

Boyce describes implants useful for “the repair or replacement of ligaments, tendons and/or cartilage.” Ex. 1006 ¶2. The implants are made from flexible elongated elements, such as bone, tendons, ligaments, or

synthetic polymeric fibers. *Id.* ¶ 25. The elongated elements are aligned along their longitudinal axis to provide, for example, woven, knitted, braided, or twisted structures. *Id.* ¶¶ 10, 20. To illustrate, Figures 1A and 1B are reproduced below.

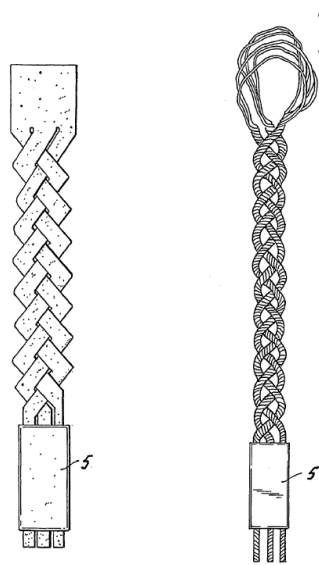


Fig. 1a **Fig. 1b**

Figure 1A shows an elongated section of bone that has been cut to provide three elongated elements arranged in a braid, and Figure 1B shows elongated elements formed into yarns that are arranged in a braid. *Id.* ¶ 24. The elongated elements have “connective tissue-healing activity,” which means they have “the ability . . . to participate in the repair, regeneration, healing, etc., of connective tissue, e.g., bone, ligament, tendon or cartilage.” *Id.* ¶ 15. The implants comprising the elongated elements can be used in various surgical procedures, including the repair of the vertebral column as well as the repair of ligaments or tendons in the spine, hand, elbow, knee, foot, and ankle. *Id.* ¶ 63.

2. *Analysis of Claims 5 and 7–11*

We turn now to the claims. Claims 5 and 7–11 depend directly from independent claim 1. As discussed above, we are persuaded that claim 1 would have been obvious over Van Kampen and Marshall. *See supra* Part III.C.2.a. Of relevance here, we are persuaded in particular that Petitioner’s proposed combination of Van Kampen and Marshall teaches or suggests all the limitations of claim 1, including a “first bone,” a “second bone,” and a “joint.” *See id.* Dependent claims 5 and 7–11 require the first and second bones and the joint to be part of “a foot,” “a shoulder,” “a spine,” “a hand,” “a hip,” and “an elbow,” respectively.

For these limitations, Petitioner acknowledges that an “express disclosure of stabilizing these areas of the body is absent” in Van Kampen, but at the same time notes that Van Kampen “does not limit the use of [its] device to any particular region of the body.” Pet. 57, 62 (citing Ex. 1005, 1:15–21, 5:9–13); *see also* Ex. 1005, 5:9–13 (“The selection of the appropriate biological tissue to reconstruct or repair a particular tendon or ligament is well within the level of ordinary skill in the field of orthopedic surgery and does not form part of the present invention.”). Petitioner thus relies additionally on Boyce, asserting that “Boyce teaches using an orthopedic implant for the treatment of spinal disorders, as well as for the repair and replacement of ligaments in the elbow, knee, foot, hand, and ankle, ‘or any other anatomical location.’” Pet. 62 (citing Ex. 1007 ¶¶ 2, 63). Petitioner contends that an ordinarily skilled artisan “would have found it obvious to combine the teachings of Van Kampen’s device, capable of use on a variety of ligaments in the body, with Boyce’s description of performing similar procedures throughout the body.” *Id.* at 58.

As support, Petitioner asserts that Van Kampen and Boyce “disclose similar implantation devices used for treating damaged ligaments and tendons.” Pet. 58. Petitioner also asserts that, “like Van Kampen, Boyce teaches the use of implants for the knee, but unlike Van Kampen, Boyce further teaches the use of the similar implants in the spine, hand, elbow, and foot.” *Id.* at 57–58 (citing Ex. 1005, 2:23–40; Ex. 1007 ¶¶ 2, 63). Petitioner points to Van Kampen’s characterization of its discussion of ligament reconstruction in the knee as “[a]n example,” and further asserts that “[i]t would have been natural for a [person of ordinary skill in the art] to look to Boyce to determine other suitable applications for the device disclosed in Van Kampen because of this overlap in disclosure.” *Id.* at 57, 59 (citing Ex. 1005, 1:15–21). Petitioner adds that the ordinarily skilled artisan “would have understood that ligament repair and reconstruction regions in the knee, foot, shoulder, spine, hand, hip, and elbow were equivalents at the time of the alleged invention of the ’449 Patent,” and “would also have been able to make any necessary modifications to the device or methods disclosed in Van Kampen and Marshall to implement a similar repair to a ligament in the foot, shoulder, spine, hand, hip, and elbow.” *Id.* at 59, 62. Petitioner relies on the declaration testimony of Dr. Jordan. *Id.* at 58–64 (citing Ex. 1002 ¶¶ 129, 132–134, 137–152).

Patent Owner cross-references its analysis with respect to Petitioner’s asserted ground of obviousness over Van Kampen and Marshall, and responds that an ordinarily skilled artisan “would not have used Marshall’s ACL primary repair at the time of the invention and would have instead used ACL reconstruction with a graft.” PO Resp. 51. Patent Owner also asserts that Petitioner’s declarant “Dr. Jordan does not provide any rationale for

why a [person of ordinary skill in the art] would use repair instead of reconstruction of these other body parts based on Boyce when the combination of Van Kampen and Marshall so clearly leads a [person of ordinary skill in the art] to reconstruction in the context of the ACL.” *Id.*; *see also id.* at 52 (“ACL primary repair was abandoned at the time of the invention, which indicates that it did not provide successful or predictable results and would not have motivated a [person of ordinary skill in the art] to modify Marshall’s ACL primary repair to apply to ligaments in other parts of the body.”). Patent Owner adds that an ordinarily skilled artisan “would have understood that there were multiple biological and surgical requirements for various ligaments in the body that were specific, and that implants and techniques could *not* be extrapolated directly from one body part to another.” *Id.* at 51–52. Patent Owner relies on the declaration testimony of Dr. Pedowitz. *Id.* (citing Ex. 2001 ¶¶ 113–115).

In the context of combining Van Kampen and Marshall’s ACL reconstruction, Patent Owner further asserts that “Dr. Jordan does not propose a rationale for using a second fastener for the tendon in Marshall’s ACL reconstruction, or for why Marshall’s ACL reconstruction should be extended to other parts of the body.” PO Resp. 52–53. In addition, Patent Owner states that “Petitioner does not assert Marshall’s ACL reconstruction in its combination of Van Kampen with Marshall in its Petition.” *Id.* at 53. Patent Owner concludes, “Thus, Dr. Jordan and the Petition do not explain how Boyce provides claim element [1.4] missing from the combination of Van Kampen and Marshall’s ACL reconstruction,” and, “[s]ince at least this element of claim 1 is missing from the combination of Van Kampen, Marshall and Boyce, claim 1 is not obvious for the same reasons advanced

. . . with respect to Ground 1,” namely, obviousness over Van Kampen and Marshall. *Id.*

Petitioner replies that Patent Owner’s “argument contradicts [its] own ‘449 patent claims and specification.” Pet. Reply 23. Petitioner asserts that “[d]ependent claims 5 and 7-11 of the ‘449 patent claim a surgical method for ligament augmentation wherein the first and second bones and the joint are part of the knee, foot, shoulder, spine, hand, hip and elbow,” but “nowhere in the ‘449 patent does the specification describe or show how ligament augmentation would be done on any of these body parts.” *Id.* at 23–24. Petitioner contends that “[a]ny argument that a [person of ordinary skill in the art] would be incapable of adapting the device disclosed in Van Kampen to these other body parts is undercut by the ‘449 patent itself, which expects the [person of ordinary skill in the art] to do just that.” *Id.* at 24.

Patent Owner counters that “Petitioner’s improper attempt to use the ‘449 patent as a guide for what a [person of ordinary skill in the art] would have known or considered fails,” and, “[s]o, too, does Petitioner’s attempt to extrapolate this argument to the teachings of Van Kampen.” PO Sur-reply 22. According to Patent Owner, “Dr. Jordan’s statements that a [person of ordinary skill in the art] would have known how to apply Van Kampen’s device to augment various ligaments in the foot, shoulder, spine, hand, hip and elbow are unsubstantiated.” *Id.*

We disagree with Patent Owner. In particular, Patent Owner’s argument that an ordinarily skilled artisan would not have used Marshall’s ACL primary repair at the time of the invention is unavailing. *See* PO Resp. 51; *see also id.* at 31 (“At the time of the invention, a [person of ordinary skill in the art] would have known that ACL primary repairs, including

Marshall's ACL primary repair method, had been abandoned in the art.'"). As discussed above with respect to Petitioner's asserted ground of obvious over Van Kampen and Marshall, Patent Owner's cited references do not teach away from using ligament repair, at least for a subset of patients. *See supra* Part III.C.2.a.viii.(B). Accordingly, contrary to Patent Owner's position, Petitioner need not provide a reason for using repair instead of reconstruction. PO Resp. 51.

Similarly, Petitioner need not provide "a rationale for using a second fastener for the tendon in Marshall's ACL reconstruction, or for why Marshall's ACL reconstruction should be extended to other parts of the body." *See* PO Resp. 52–53. As explained above, Petitioner does not rely on Marshall's teachings regarding ACL *reconstruction* as a basis for its asserted ground of obviousness over Van Kampen, Marshall, and Boyce. *See* PO Resp. 41 ("Petitioner's obviousness rationale does not include ACL reconstruction."). Instead, Petitioner relies on Marshall's teachings regarding ACL *repair*. Patent Owner's argument regarding Marshall's ACL reconstruction therefore also is unavailing.

As for Patent Owner's argument that "there were multiple biological and surgical requirements for various ligaments in the body that were specific, and that implants and techniques could *not* be extrapolated directly from one body part to another," we disagree. *See* PO Resp. 51–52. "The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference," but, "[r]ather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *See In re Keller*, 642 F.2d 413, 425 (CCPA 1981). Further, "[a] person of ordinary skill is also a

person of ordinary creativity, not an automaton.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007). In this case, Van Kampen states that “[t]he selection of the appropriate biological tissue to reconstruct or repair a particular tendon or ligament is well within the level of ordinary skill in the field of orthopedic surgery.” Ex. 1005, 5:9–13. Boyce describes “a wide variety of orthopedic . . . surgical procedures,” such as the repair of ligaments in the spine, hand, elbow, knee, foot, ankle, “or any other anatomical location.” Ex. 1007 ¶ 63. We find that an ordinarily skilled artisan, in repairing a ligament in any part of the body, such as the foot, shoulder, spine, hand, hip, or elbow, would have made the necessary modifications to accommodate Van Kampen’s augmentation device to realize the advantages of using Van Kampen’s augmentation device in parts of the body other than the knee.

For the reasons given above, we are persuaded by Petitioner’s argument and evidence that the proposed combination of Van Kampen, Marshall, and Boyce teaches or suggests the recited limitations of claims 5 and 7–11. On this record, we also are persuaded that Petitioner’s proffered reasoning for using Van Kampen’s device in the treatment of a ligament in a foot, a shoulder, a spine, a hand, a hip, or an elbow, as taught or suggested by Boyce, supports the legal conclusion of obviousness. *See Kahn*, 441 F.3d at 988; *Intel*, 61 F.4th at 1381 (explaining that the petitioner need only show that the proposed combination would have provided a “suitable option”).

3. Summary

In view of the foregoing, we determine that Petitioner has demonstrated by a preponderance of the evidence that claims 5 and 7–11 would have been obvious over Van Kampen, Marshall, and Boyce.

E. Remaining Grounds

Petitioner asserts that claims 1–4, 6 and 8 of the ’449 patent would have been obvious over Van Kampen, Marshall, and Lambrecht. Pet. 46–57. Petitioner also asserts that claims 5, 7, and 9–11 would have been obvious over Van Kampen, Marshall, Lambrecht, and Boyce. *Id.* at 64–66.

As discussed above, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–4 and 6 would have been obvious over Van Kampen and Marshall, and that claims 5 and 7–11 would have been obvious over Van Kampen, Marshall, and Boyce. *See supra* Parts III.C, III.D. Because these two asserted grounds are dispositive as to all the challenged claims, namely, claims 1–11, we need not reach either the asserted ground based on Van Kampen, Marshall, and Lambrecht or the asserted ground based on Van Kampen, Marshall, Lambrecht, and Boyce with respect to these claims. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (holding that a petitioner “is entitled to a final written decision addressing all of the claims it has challenged”); *Bos. Sci. Scimed, Inc. v. Cook Grp. Inc.*, 809 F. App’x 984, 990 (Fed. Cir. 2020) (nonprecedential) (recognizing that the “Board need not address issues that are not necessary to the resolution of the proceeding” and, thus, agreeing that the Board has “discretion to decline to decide additional instituted grounds once the petitioner has prevailed on all its challenged claims”). Accordingly, we do not reach Petitioner’s arguments that claims 1–4, 6, and 8 would have been obvious over Van Kampen, Marshall, and Lambrecht, or that claims 5, 7, and 9–11 would have been obvious over Van Kampen, Marshall, Lambrecht, and Boyce.

IV. CONCLUSION

We determine that Petitioner has demonstrated by a preponderance of the evidence that claims 1–11 of the '449 patent are unpatentable as follows.⁹

References	35 U.S.C. §	Claims	Claims Shown Unpatentable	Claims Not Shown Unpatentable
Van Kampen, Marshall	103	1–4, 6	1–4, 6	
Van Kampen, Marshall, Boyce	103	5, 7–11	5, 7–11	
Van Kampen, Marshall, Lambrecht	103	1–4, 6, 8 ¹⁰		
Van Kampen, Marshall, Lambrecht, Boyce	103	5, 7, 9–11 ¹¹		
Overall Outcome			1–11	

⁹ Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this Decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. §§ 42.8(a)(3), (b)(2).

¹⁰ We do not reach whether claims 1–4, 6, and 8 are unpatentable based on this ground because we determine that claims 1–4 and 6 are unpatentable based on the ground of obviousness over Van Kampen and Marshall, and that claim 8 is unpatentable based on the ground of obviousness over Van Kampen, Marshall, and Boyce.

¹¹ We do not reach whether claims 5, 7, and 9–11 are unpatentable based on this ground because we determine that they are unpatentable based on the ground of obviousness over Van Kampen, Marshall, and Boyce.

V. ORDER

In consideration of the foregoing, it is hereby
ORDERED that claims 1–11 of the '449 patent are held *unpatentable*;
and

FURTHER ORDERED that, because this is a Final Written Decision,
parties to the proceeding seeking judicial review of the decision must
comply with the notice and service requirements of 37 C.F.R. § 90.2.

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